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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,334	04/09/2001	Elmar Peschke	1348	8721

7590 04/22/2003  
Striker Striker & Stenby  
103 East Neck Road  
Huntington, NY 11743

EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/22/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/701,334

Applicant(s)

PESCHKE ET AL.

Examiner

B. Dell Chism

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

This Office Action is in response to Paper No. 7, filed 24 January 2003, wherein Applicants canceled claims 1-4 and added claims 5-13.

Newly submitted claims 5-8 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly presented claims 5-8 are drawn to a pharmaceutical composition, whereas original claims 1-4 were all drawn to a method of use claims (which is how they were examined over the art in the previous Office action) and not to a pharmaceutical composition, per se.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 5-8 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 9-13 are presented for examination on the merits.

#### ***Rejections/Objections***

#### ***New/Maintained/Withdrawn***

#### ***Claim Rejections - 35 USC § 112***

1. (Maintained) Claims 9-13 are rejected under 35 U.S.C. 112, for the reasons set forth in the previous office action concerning canceled claims 1-4 which are restated below.

The Applicants are not enabled for the many compounds that would fall within the scope of the claimed invention regarding "at least one compound," nor the claimed methods of

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using the many compounds/compositions. The art teaches a level of unpredictability regarding melatonin activity for the purpose of regulating or inhibiting insulin release via beta cell islets, i.e., Bailey *et al.* 1974 (cited in previous office action). The instant specification only discloses in vitro melatonin applications and preparations for treatment of rat pancreatic cells. There are inadequate amounts of working examples in the specification, wherein it is obvious that the scope of the claimed invention would encompass all possible compounds and formulations that would translate from in vitro experiments to in vivo administration. The lack of predictability and lack of working examples in the specification would require undue experimentation for one skilled in the art to make and/or use the invention commensurate with the breadth of the claimed inventions other than melatonin.

***Claim Rejections - 35 USC § 102***

2. (Maintained) Claims 9-10 are rejected under 35 U.S.C. 102(b) for the reasons set forth in the previous office action concerning canceled claims 1-4 which are restated below.

Claims 9-10 are anticipated by Bailey *et al.* (Hormone Res. 5:21-28), wherein Bailey *et al.* discloses in vitro assays of the use of melatonin for reduction in basal insulin secretion of rat pancreas, just as instant case. Bailey *et al.* also discloses the administration of melatonin (an "at least one compound") via saline solution, which is a common liquid carrier used for pharmaceutical purposes. This rejection is necessitated via Applicants' amendments.

***Claim Rejections - 35 USC § 103***

3. (Maintained) Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey *et al.* (Hormone Res. 5:21-28) as applied to claim 9-13 above, and further in view of Peschke *et al.* 1997 (J. Peneal Res. Vol. 23, pages 156-163). Bailey *et al.* discloses in vitro assays of the use of melatonin for reduction in basal insulin secretion of rat pancreas, just as instant case. Bailey *et al.* also discloses the administration of melatonin (an "at least one compound") via saline solution, which is a common liquid carrier used for pharmaceutical purposes. Peschke *et al.* teach a composition of melatonin for in vitro inhibition of pancreatic production of insulin wherein the melatonin is applied via diluent. These documents, together, beneficially teach that melatonin effectively reduces insulin production and/or secretion. The adjustment of particular conventional working conditions (e.g. dosages), is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

4. Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Conclusion*

No claims are allowed. Action is made FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism  
21 April 2003

Christopher S.F. Low

CHRISTOPHER S. F. LOW  
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